

Appl. No. 10/721,877
Amendment dated: January 5, 2006
Reply to OA of: October 5, 2005

REMARKS

This is in response to the Official Action of October 5, 2005. Applicants note with appreciation the indication of allowable subject matter at page 6 of the outstanding Official Action. Specifically, the Official Action states that claim 3 would be allowable if rewritten in independent format to including all of the limitations of the base claim and any intervening claims. However, Applicants respectfully submit that the claims presented herein are patentably distinct from the prior art references of record and are therefore clearly allowable.

Applicants have amended the claims in order to more precisely define the scope of the present invention and taking into consideration the outstanding Official Action. First, the specification of the present application has been amended in order to address the objections to the disclosure set forth in the Official Action. The Official Action urges that the brief description of Figure 1 on page 6 of the specification does not appear to correlate with Figure 1. Accordingly, Applicants have amended the brief description of Figure 1 to recite that the graph depicts the variation of the viscosity in gel samples of 15wt%, 20wt%, 25wt% and 33wt% in example 8. Additionally, the Official Action notes that no brief description of Figure 8 appears in the specification. Accordingly, Applicants have amended the specification to include a brief description of Figure 8. In light of these amendments to the specification, Applicants respectfully request that the objection to the disclosure be withdrawn.

Applicants have also amended the claims in order to address the objections to the claims as set forth in the outstanding Official Action. The Official Action urges that claim 5 is of improper independent form for failing to further limit the scope of the a previous claim. Accordingly, Applicants have amended claim 1 to recite that R_2 is C_{7-30} alkyl substituted or unsubstituted with functional groups or hydrogen. The Official Action also objects to claims 6 and 7 because the claims do not identify the type of molecular weight. Applicants respectfully submit that one of ordinary skill in the art would understand what is meant by molecular weight without the need to specify whether the molecular weight is weight average molecular weight or number average molecular

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weight and therefore request that this objection be withdrawn

Applicants have also amended claim 1 in order to more precisely define the scope of the present invention. Specifically, Applicants have amended claim 1 to incorporate the limitation of claim 9. Claim 9 has therefore been canceled without prejudice or disclaimer. Applicants now respectfully submit that all claims currently pending in the present application are in full compliance with the requirements of 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claims 1, 2, 4-7, 9 and 10 under 35 U.S.C. §102(e) as being anticipated by Seo (U.S. Patent No. 6,616,941), Seo (U.S. Pub. No. 2003/0017206), Seo (U.S. Pub. No. 2005/0201972) or Fowers have each been carefully considered but are most respectfully traversed in light of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The Official Action urges that each of the Seo references and the Fowers reference disclose every element claimed in claim 1, and further urges that, with respect to claims 5, 9 and 10, the properties claimed would be inherent to the composition since the polymers claimed are the same as those disclosed in the references. Applicants specifically traverse this statement.

The difference between the present invention and the inventions disclosed in the

prior art references lies in the thermo-sensitive characteristic of the presently claimed invention. Contrary to the assertion made in the Official Action, this thermo-sensitive property would not be inherent to the inventions disclosed in the prior art references of record.

Claim 1 has been amended to additionally recite that the polymer is thermo-sensitive polymer having an LCST ranging from 15°C to 30°C. LCST stands for lower critical solution temperature, which is the temperature at which a biodegradable block copolymer undergoes the transition from a copolymer that is soluble in water to a semi-solid block copolymer (e.g., gel, emulsion, etc.). As explained in the specification of the present invention, the thermo-sensitive polymer claimed therein must have a biodegradability and adequate LCST in order to accomplish the objectives of reducing harm to tissues, simplifying the implantation procedure or the manufacturing process and reducing the burst effect for drug release. The present invention recognizes that these objectives are best accomplished when the LCST of the block copolymer is between 15°C and 30°C.

The specification of the present application also recognizes that the LCST is affected by percentage of hydrophilic and hydrophobic units of the block copolymer. As explained at page 6, line 22 through page 7, line 20, the LCST of the polymer of the present invention can be increased by increasing the percentage of the hydrophilic unit, while the LCST of the polymer of the present invention can be decreased by increasing the percentage of the hydrophobic unit. Therefore, it follows that the present invention requires a delicate balance of the percentage of each unit of the block copolymer in order to produce a copolymer with an advantageous LCST between 15°C and 30°C.

To the contrary, the prior art references do not make this recognition nor do they discuss the balance of hydrophilic and hydrophobic units required to achieve this beneficial LCST range. In fact, none of the prior art references even mention LCST or its significance in providing a suitable block copolymer for use as a drug release system. This property can also not be said to be inherent to all block copolymers disclosed in the prior art references because, as discussed above, only those block copolymers striking

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the correct balance between hydrophilic and hydrophobic units will exhibit an LCST in the range of 15°C to 30°C. As none of the prior art references discuss this balance, it is clear that they also fail to disclose an LCST range as claimed in claim 1 of the present application.

Applicants have discovered that a block copolymer that is thermo-sensitive and that has a LCST between the range of 15°C and 30°C produces an improved block copolymer for a drug release system. There is no recognition of this fact in the prior art references. Therefore, it is clear that, absent a motivation for specifically selecting those specific percentages that lead to an LCST in the claimed range, the use of the prior art references to support a prior art rejection under either §102 or §103 would necessitate improper hindsight reliance on the disclosure of the present invention. That is to say, because none of the prior art references recognize the benefits of a specific LCST or the affect of unit percentages on the LCST, the Official Action would only be able to come to the conclusion that the prior art references meet this limitation by using the disclosure of the present invention as a road map. It is well established that this kind of hindsight reconstruction is impermissible (see, e.g., *In re Fritch*, 23 USPQ 1780, 1784(Fed Cir. 1992)), and therefore a §102 rejection based on the above prior art references must be improper. Accordingly, Applicants respectfully request that these rejections be withdrawn.

The rejection of claims 1, 4-7, 9 and 10 under 35 U.S.C. §103(a) as obvious over Fowers and the rejection of claim 8 under 35 U.S.C. §103(a) as being unpatentable over Seo (US 2005/0201972) have each been carefully considered but are most respectfully traversed in light of the amendments to the claims and the following comments.

As discussed in detail above, claim 1 has been amended to recite that the polymer is thermo-sensitive polymer having an LCST ranging from 15°C to 30°C and this feature is neither disclosed nor suggested by the prior art references. It would require impermissible hindsight to construct the presently claimed invention from the prior art references, and therefore the prior art rejections based on these references are improper. Further, because claims 4-10 depend from claim 1, which has been shown

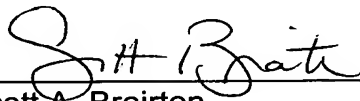
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above to be clearly allowable over the prior art references of record, the claims depending therefrom must also be allowable. Accordingly, Applicants respectfully request that these rejections be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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